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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,748	09/09/2003	Paul J. Thompson	11576.51USC1	3397
21127	7590	12/14/2005	EXAMINER	
KUDIRKA & JOBSE, LLP			HOUSTON, ELIZABETH	
ONE STATE STREET				
SUITE 800			ART UNIT	PAPER NUMBER
BOSTON, MA 02109			3731	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/658,748	THOMPSON, PAUL J.
	Examiner Elizabeth Houston	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 September 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>102705</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 10-21, 24-29 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-5, 10-13, and 15 of U. S. Patent No. 6,623,491. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the application are merely broader than the patent claims.

3. Claims 10-13, 16-18, 20-22, 24-25, 27 and 29 of this application conflict with claims 1-8, 10-11, 13-14, and 19 amended on 09/13/2004 of Application No. 09/954,763. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of

demarcation between the applications. See MPEP § 822. Applicant states in the Remarks dated 09/17/05 that the claims of instant application do not recite an identical or analogous limitation to the claims in the conflicting application. Examiner asserts that the “treatment site” found in Claim 10 of the instant is analogous to the “stent mounting location” found in claim 1 of the conflicting application. Therefore the rejection is upheld.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-12, 14, 15, 17, 20-23, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mische et al. (USPN 5,279,546).

6. As to claims 10, 20, 21, and 27, Mische discloses a treatment system (Figures, 1-3), comprising: an elongated outer member (70) having a distal end and a proximal end, the outer member having a wall that defines a first lumen (126, 128, 130, 132); an elongated inner member (72) having a distal end and a proximal end, the inner member having a wall that defines a second lumen (142, 144, 146), the inner member being received within the outer member (Col4, line 40-41); the outer member being sized to pass through a body lumen with the distal end being advanced toward a treatment site and with the proximal end being external to the body lumen for manipulation by an

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operator; the inner member having a treatment region at the distal end of the inner member (86); a fluid passage is defined *between* the wall of the inner member and the wall of the outer member (126, 128, 130, 132); a plurality of circumferentially spaced-apart structures (134, 136, 138, 140) disposed along a majority of the length of the fluid passage *between* the wall of the inner member and the wall of the outer member with the circumferentially space-apart structures spacing the wall of the inner member from the wall of the outer member; and a port in communication with the fluid passage (46) (Col 4, line 9-10).

7. As to claim 11 and 27, the spaced apart structures extend an entire length from the proximal end of the outer member to the treatment region (the treatment region being defined by balloons (74) and (86). As to claim 12 and 22, the spaced apart structures are disposed to maintain the inner member centrally positioned within the outer member and prevent the inner member from moving radially (Col 5, lines 32-36). As to claim 23, the spaced apart structures prevent the inner member from contacting the outer member. As to claims 13 and 24, the spaced apart structures are carried on the wall of the inner member and extend radially outward towards the outer member. When the device, as a whole is delivered to the treatment site, the outer and inner catheter will travel together and so the spaced apart structures will be carried on the inner member. As to claim 14, the guidewire is element (11). As to claim 15, the spaced apart structures are shaped to define voids that extend the length of the fluid passage. As to claim 17 and 24, the base portion of the spaced apart structures is connected to the wall or the lumen-defining portion of the inner member and the

opposite end engages the wall of the outer member. Although the inner catheter is not fixedly connected to the outer catheter, it is, nonetheless, connected. Since the catheters are assembled together as one structure, they are thus considered connected.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 20 and 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Krivoruchko et al. (USPN 6,786,918).

10. Krivoruchko discloses a catheter device comprising an elongated outer member (26) having an outer member length and an inner surface that defines a lumen (30), the outer member being sized to be passed through a body lumen; an elongated inner member (24) having an inner member length and positioned within the lumen of the outer member (see figure 2), the inner member including a lumen-defining portion; and a plurality of circumferentially spaced-apart structures (62) that extend between the lumen-defining portion of the inner member and the inner surface of the outer member, the circumferentially spaced-apart structures have an uninterrupted length and are coextensive and with a majority of the lengths of the inner and outer members (Col 4,

line25-26). The spaced-apart structures include a base portion connected to the inner member, and an opposite end that engages the inner surface of the outer member (see Figure 5). The base portions of the spaced apart structures are integral with the lumen-defining portion of the inner member, and the opposite ends are rounded (see Figure 5).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 10-19 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bevier (USPN 6,190,393) in view of Krivoruchko et al (USPN 6,786,918).

13. Bevier discloses a treatment system, comprising: an elongated outer member (64) having a distal end and a proximal end, the outer member having a wall that defines a first lumen; an elongated inner member (24) having a distal end and a proximal end, the inner member having a wall that defines a second lumen (32), the inner member being received within the outer member; the outer member being sized to pass through a body lumen with the distal end being advanced toward a treatment site and with the proximal end being external to the body lumen for manipulation by an operator; the inner member having a treatment region at the distal end of the inner member (14); a fluid passage defined *between* the lumen defining portion (32) of the

inner member and the inner surface of the outer member (30, Col 4, line 44)); a port in communication with the fluid passage (26); and a guidewire (32).

14. Beveir does not disclose a spacer structure.
15. Krivoruchko discloses a plurality of circumferentially spaced-apart structures as stated above. In addition Krivoruchko discloses that the spaced apart structures maintain that the inner member is centrally positioned within the outer member (Col 4, line 37). The spaced apart structures are carried on the wall of the inner member, extend radially outward, and define voids (68A-F).
16. It would have been obvious at the time of the invention to one of ordinary skill in the art to combine the spacer structure into the invention of Beveir. The spacer structure decreases space between the members to prevent radial deflection (Col 4, line 37) while at the same time providing lumens for inflating and deflating the balloon. The spacer structure would enhance the invention of Beveir by providing extra support so that the tubular members do not collapse onto each other and so that the tubular members can easily slide independently of each other.

Response to Arguments

17. Applicant's arguments filed 09/16/05 have been fully considered but they are not persuasive.
18. Regarding the provisional double patenting rejection of conflicting claims with Application No. 09/954,763, Applicant states that the claims of instant application do not recite an identical or analogous limitation to the claims in the conflicting application.

Examiner asserts that the “treatment site” found in Claim 10 of the instant is analogous to the “stent mounting location” found in claim 1 of the conflicting application. Therefore the rejection is upheld.

19. Regarding claim 10, Applicant has stated that Mische does not disclose a fluid passage defined *between* the wall of the inner catheter and the wall of the outer catheter, but rather one that is *within* the outer catheter. Examiner disagrees. The fluid passage exists in between or in the middle of two points defined by the wall of the outer catheter and the wall of the inner catheter. Examiner believes that applicant is interpreting the term “between” in a narrow sense of the word. For example, in a row of letters A through M, any letters B through L are between A and M, even if they are not adjacent or touching both A and M. The rejection as anticipated by Mische is respectfully upheld.

20. Regarding the rejection as anticipated by Krivoruchko, Applicant states that by also using Krivoruchko in combination with Bevier, examiner is admitting that Krivoruchko does not in fact anticipate the limitations of the claims. Regarding claims 20 and 24-29, Krivoruchko is relied on to anticipated the claims as stated above. In the combination of Bevier in view of Krivoruchko, examiner is relying on Krivoruchko as a teaching reference. It is in fact Bevier, not Krivoruchko, that is missing particular elements, and Krivoruchko is teaching the use of those missing elements as stated above.

21. As to the combination of Bevier in view of Krivoruchko, applicant states that the examiner has failed to make a *prima facie* case of obviousness. Applicant is basing this

fact on Applicant's narrow definition of "between" Applicant states that the inflation lumen (30) is not defined between the wall of the balloon catheter shaft (24) and outer catheter (64). In the rejection, examiner has shown that the wall of the inner shaft is that which defines the second lumen (32), as stated in claim 10, and therefore the inflation lumen does in fact exist *between* the wall of the inner member and the wall or lumen defining portion of the inner member.

22. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is clearly stated in the Krivoruchko reference (Col 4, lines 35-42) (see rejection above).

Conclusion

23. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

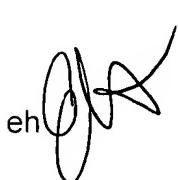
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh


ANHTUANT.NGUYEN
SUPERVISORY PATENT EXAMINER


12/12/05